UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

January 29, 2016

DP BARCODE: 430143

MRID(s): 49689403

SUBJECT: Corning Antimicrobial Particles

REG. NO. OR FILE SYMBOL: 89661-E

DOCUMENT TYPE: Acute Toxicity Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
042401	1317-38-0	Copper (II) oxide

TEST LAB: Technology Sciences Group, Inc

SUBMITTER: Corning, Inc

GUIDELINE(s): 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600.

COMMODITIES: N/A

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** 2 / 17/2016

COMMENT: This product is for non-food use

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MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No. 89661-E
Product Name: Corning Antimicrobial Particles
DP Barcode: 430143

TO: Eric Miederhoff / Karen Leavy
PM Team # 31

FROM: Boris S. Yurchak, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Corning, Inc
Action code: (A540) New product; non-fast track
Due out date: February 13, 2016

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Cupric oxide	33.0
Other Ingredient(s)*	67.0
TOTAL	100.0

BACKGROUND:

The registrant is submitting a waiver request to support the registration of the subject product, Corning Antimicrobial Particles, EPA Reg. No. **89661-E**. The waiver request is provided in MRID 49689403 for all six toxicity endpoints. The waiver was prepared by Technology Sciences Group, Inc. The product targeted in the waiver was the subject product. The product is designed to protect paint and paint film from mold, mildew and bacteria that cause deterioration.

The data package included:

1. Cover letter from Registrant to EPA, dated 09/23/2015.
2. Transmittal document, dated 09/23/2015.
3. Basic Confidential Statements of Formula (CSF), dated 09/23/2015.
4. Proposed label, dated 09/23/2015.

FINDINGS:

1. The subject product is made by combining cupric oxide (II) with a solid inert under high temperatures. The molten mixture is then rapidly cooled and milled into a powder.

2. In general, waivers presume the toxic properties of the subject product are due exclusively to the toxicity profile of the active ingredient. In particular:
    a. the potential for oral (81-1), dermal (81-2) and skin (81-5) exposure is very low because the copper ionizes cannot readily be separated from the solid inert matrix;
    b. the waiver for an acute inhalation study (81-3) is based on the fact that the subject product is mixed into paint or plastic before consumers can interact with it;
    c. The waiver for primary eye irritation (81-4) is based on known effects of the active ingredient. Ocular exposure to dust or powders, that may hurt the eyes as a result of mechanical irritation, is ignored because this is not unique to copper (II) oxide;
    d. The waiver for dermal sensitization (81-6) is based on the known property of the active ingredient.

3. The waiver request is not granted due to the following:
    a. a sole active ingredient is not substantially similar to the subject product due to structural deficiencies;
    b. the applicant did not demonstrate that the subject product cannot be ingested, inhaled and the product design prevents dermal and eye exposure;
    c. the readiness of separation the copper ionizes from the solid inert matrix is not a reason for an assessment of the toxicity impact of the subject product; this feature relies only to the active ingredient impact;
    d. mechanical irritations caused by the subject product (glass particles) cannot be ignored;
    e. a feature of an application pattern of the subject product cannot be a criterion for a waiver.

Overall, the waivers for all endpoints are not granted because the substantiations provided do not follow the OPP Document: Guidance for Waiving or Bridging of Mammal Acute Toxicity tests for pesticides and Pesticide Products (Acute Oral, Acute Dermal, Acute Inhalation, Primary Eye, Primary Dermal, and Dermal Sensitization). EPA, March 1, 2012.

4. The acute toxicity profile for EPA Reg. No. **89661-E** is currently:

GRN	Study	MRID	Toxicity Category		Status
			Waiver request	Comments	
81-1	Acute Oral Toxicity	49689403	IV	NG	Data gap
81-2	Acute Dermal Toxicity	49689403	IV	NG	Data gap
81-3	Acute Inhalation Toxicity	49689403	III	NG	Data gap
81-4	Primary Eye Irritation	49689403	III	NG	Data gap
81-5	Primary Dermal Irritation	49689403	III	NG	Data gap
81-6	Dermal Sensitization	49689403	Non-sensitizer	NG	Data gap

NG – not granted

CONCLUSION:

The acute toxicity requirements have not been satisfied for the subject product.